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December 19, 2014

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Scientific Advisory Board

Annette Vietti-Cook
Office of the Secretary
Secretary of the Commission
U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-0001

Meghan E. Gutierrez
Chief Executive Officer

National Headquarters
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Re: Docket ID NRC-2008-0175
Medical Use of Byproduct Material—Medical Event Definitions, Training and
Experience, and Clarifying Amendments; Proposed Rule

LRF Helpline
800-500-9976
Helpline@lymphoma.org

Dear Secretary Vietti-Cook:

The Lymphoma Research Foundation (LRF) is the nation's largest non-profit organization devoted exclusively to funding innovative lymphoma research and providing people with lymphoma and healthcare professionals with up-to-date information about this type of cancer. LRF's mission is to eradicate lymphoma and to serve those touched by this disease. We appreciate the opportunity to respond to the Commission's request for comments regarding the proposed rule to amend NRC regulations concerning the medical use of byproduct material. The Foundation supports the NRC's efforts to update its regulations to reflect changes in clinical practice and advances in medical technology. LRF does not want to see the affect of any regulation to prove too burdensome for practitioners and result in limited access to safe and effective pharmaceuticals among the lymphoma population.

In its Notice of Proposed Rulemaking, the NRC specifically requested comment on whether regulations "discourage licensees from using certain therapy options or otherwise adversely impact clinical practice..." LRF acknowledges the importance of training and experience requirements when dealing with therapeutic radiopharmaceuticals and respectfully requests the NRC consider regulatory framework that balances the importance of training and safety while not creating undue hardship on hematologists and oncologists who wish to administer these therapies. A lymphoma patient faces a difficult and complex process as it relates to their diagnosis and treatment. Lymphoma is unique in that there are more than 67 subtypes of the disease, each considered to be a rare and complex diagnosis which is notorious for recurrence. A lymphoma patient needs access to every tool in the arsenal for the management of their disease.

The Foundation appreciates the NRC's concern with whether or not the proposed regulations regarding authorized users able to administer radiopharmaceuticals adversely impact clinical practice. Every patient should have access to the treatments recommended by their doctor. To that end, doctors should not feel discouraged from prescribing or administering a treatment because of an onerous regulatory structure. We believe that the Commission must find balance between ensuring public safety during the administration of radiopharmaceuticals while not hindering access to potentially lifesaving treatment.

We commend the Commission on their efforts and appreciate the opportunity to submit our comments for consideration.

Sincerely,



Robin Roland Levy
Director, Public Policy & Advocacy
